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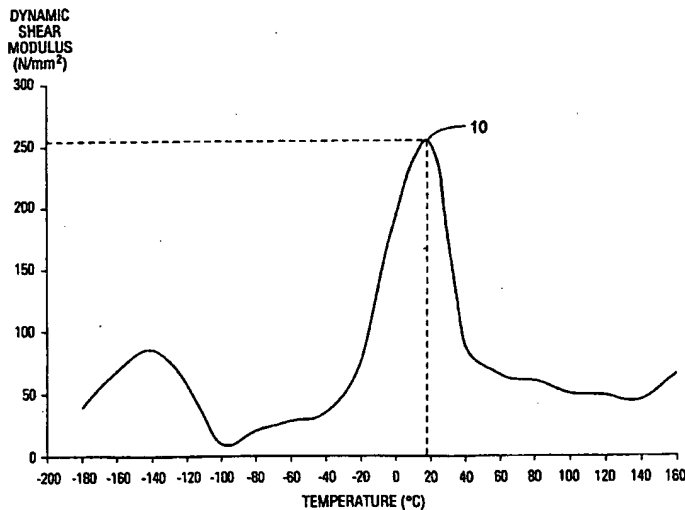
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(54) Title: PLASTICIZED NYLON BALLOONS FOR MEDICAL DEVICES



(57) Abstract

A balloon for use in a medical device made of a material comprising a plasticized polyamide having a glass transition temperature of less than about 32 °C. The polyamide may be Nylon 11 or Nylon 12, the plasticizer may be N-n-butyl benzosulfonamide, and the material may also include a stabilizer. A method for making a balloon for use in a medical device including providing a tube made of a material comprising a plasticized polyamide; disposing the tube in a balloon mold; heating the tube to a temperature within the softening temperature range of the material; pressurizing the tube to conform it with the mold, thus producing a balloon; and removing the balloon from the mold. The method also includes cooling the balloon to within the setting temperature range of the material before removing the balloon from the mold.

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## PATENT APPLICATION

### Plasticized Nylon Balloons for Medical Devices

#### BACKGROUND

The present invention relates to balloons for use in medical devices. More particularly, the present invention relates to medical balloons mounted on the distal end of catheters for use in angioplasty. The requirements for expansion properties and strength of the balloons vary depending on the intended use. Therefore, the balloons must have the ability to be tailored to the particular use.

Typically, these balloons incorporated with a catheter are inserted into vessels with fluoroscopic guidance to the site of vascular obstruction. The balloon must be easily foldable to provide a low profile to allow insertion through the sheath and guiding catheter and for crossing a lesion. Once there, the balloon is inflated to dilate the vessel lumen to increase the blood flow through the obstructed area.

High strength, flexibility and low compliance are necessary properties for the balloon to dilate the stenosis without bursting and without tearing the vessel. Additionally, for use in stent delivery, the balloon material must withstand inflation pressure of up to 20 atmospheres. The balloon expandable stents are made of stainless steel type material and are inflexible. These stents require 6 to 8 ATM pressure to expand in air. Generally, calcified lesions require 10 to 12 ATM pressure to dilate. Therefore, it is necessary for a balloon to withstand 20 ATM pressure in stenting a lesion that is calcified.

The balloon must also possess some elasticity so that the balloon is flexible and supple. At the same time, a non-distensible balloon is also desirable. By definition, a non-distensible balloon has a predictable inflation pattern and small variations in pressure do not result in great variations in diameter. This is advantageous to minimize the possibility of over-inflation which can cause hematoma or other damage to the vessel.

In the past, nylon or polyamide homopolymers (see U.S. Patent No. 4,906,244) have been used for catheter balloons. The nylon homopolymer balloons described in this patent possesses both strength to withstand high inflation pressures and can be tailored to be non-distensible. However, the nylon homopolymer material used for these balloons possesses properties which makes manufacturing these balloons difficult and expensive.

For example, nylon homopolymer material is partially crystalline in nature. This means the material will rapidly crystallize after the material has been heated to its softening temperature. Softening temperature is defined as the temperature at which a flat-ended needle of a 1mm<sup>2</sup> circular cross section will penetrate a thermoplastic specimen to a depth of 1mm under a specific load using a selected uniform rate of temperature rise. The nylon homopolymer must be heated to this temperature for the material to be blown into balloons. The effects of the crystallization are increased tensile modulus, decreased percentage of elongation, and increased tensile strength. These properties produce a relatively rigid balloon with limited utility in medical devices.

To prevent crystallization and the resulting undesirable properties, balloons fabricated from nylon homopolymers must be cooled immediately after being blown. There is only a few seconds from the time the material reaches softening temperature until 100% crystallization. Sophisticated processing apparatus therefore must be used for the material to be cooled in

this brief window. This equipment can be both costly and difficult to operate and can lead to a lower percentage of yield.

5 In addition to these processing drawbacks, the nylon homopolymer are generally hydroscopic and will therefore continue to absorb moisture. Water absorption will result in decreased tensile strength, flexural modulus and elongation. To ameliorate this situation, dryers and heaters must be used to manufacture balloons. This equipment adds expense and complexity to the whole manufacturing process.

10 In summary, strong, flexible, foldable, supple and non-distensible balloons are needed for medical devices. At the same time, a balloon material should be simple to process to avoid low balloon yields and high manufacturing expense.

#### SUMMARY

15 The present invention achieves these needs with a balloon material that is strong, flexible, foldable, supple and non-distensible and is also easy to manufacture into balloons. This invention is made of a material that includes a plasticized polyamide or plasticized polyester having a glass transition temperature of less than about 32°C and preferably between about 10°C and  
20 about 32°C. The polyamide is preferably Nylon 11 or Nylon 12 and the polyester is preferably polyethylene terephthalate (PET). The plasticized polyamide or polyester includes a plasticizer which is preferably N-n-butyl benzosulfonamide. The material preferably has a tensile modulus of elasticity of less than about 650 N/mm<sup>2</sup>, a flexural modulus of elasticity of less than  
25 about 650 N/mm<sup>2</sup> and an elongation at break of less than about 325%. Preferably, the material is Nylon 12 and includes about 13% by weight of N-n-butyl benzosulfonamide as a plasticizer and less than about 1% by weight of benzotriazole as a stabilizer.

The invention further provides a method of manufacturing balloons of the above material. In this method, a tube of plasticized polyamide or plasticized polyester is disposed in a balloon mold; heated to a temperature within the softening temperature range of the material; and pressurized to conform it to the mold, thus producing a balloon. The balloon is then cooled to a temperature within its setting temperature range and removed from the mold. The softening temperature range may be from about 240°F to about 325°F, depending on the particular balloon size. In one embodiment of the invention, the softening temperature range is from about 240°F to about 290°F and the setting temperature range is from about 100°F to about 135°F.

#### BRIEF DESCRIPTION OF FIGURES

The following is a description of the figures, in which:

Figure 1 shows a plot of dynamic shear modulus as a function of temperature for a material according to the present invention;

Figure 2 shows a plot of outside balloon diameter as a function of pressure for different diameter balloons according to the present invention;

Figure 3 shows a plot of outside balloon diameter as a function of pressure for a balloon according to the present invention together with the results for polyvinylidene fluoride (PVDF), PET and Nylon 12 homopolymer balloons;

Figure 4 shows a plot of heat flow as a function of temperature for a material according to the present invention and a Nylon 12 homopolymer; and

Figure 5 shows a schematic of an apparatus for molding balloons according to the present invention;

### DETAILED DESCRIPTION

The preferred balloons of the invention are made of polymeric materials having a glass transition temperature of less than about 32°C. The above material possesses processing characteristics that are particularly well suited for use in medical balloons. More specifically, plasticized polyamides and plasticized polyesters with a glass transition temperature of between about 10°C and about 32°C are preferable. A plasticized polyamide or polyester is a polyamide or polyester with a plasticizer added to control the glass transition temperature of the material.

Materials with the glass transition characteristics described above provide very flexible, strong balloons that are substantially non-distensible. Additionally, the material described above does not rapidly crystallize when it is heated during the balloon blowing process. Plasticized polyamide or polyester behaves like an amorphous polymer. As described in detail below, this characteristic of the present invention provides ease in processing the balloons.

The polymeric materials that may be used in the present invention includes any material that may be formed into a medical balloon and which can be modified to have a glass transition temperature of less than about 32°C. Preferred materials for use in the present invention include polyamides and polyesters. More particularly, Nylon 11, Nylon 12, and PET may be used with Nylon 12 being the most preferred material.

Generally, the glass transition temperature ( $T_g$ ) of a material may be lowered by mixing the material with a plasticizer, which is a high boiling, low molar mass compound. The glass transition temperature of the plasticized material ( $T_g^M$ ) can be calculated using the formula.

$$1/T_g^M = W_H/T_g^H + W_P/T_g^P$$

In this formula,  $T_g^H$  is the known glass transition temperature of the unplasticized polymer;  $T_g^P$  is the known glass transition temperature of the added plasticizer; and  $W_H$  and  $W_P$  are the mass fractions of the unplasticized polymer and plasticizer respectively. Using this formula together with the known glass transition temperatures of the unplasticized material and the plasticizer it is possible to produce a plasticized material with the desired glass transition temperature by varying the amount of plasticizer in the mixture.

Generally, any compound or mixture of compounds that lowers the glass transition temperature of the homopolymer material may be used as a plasticizer. Preferred plasticizers that may be used in the present invention include N-n-butyl benzosulfonamide, N-n-butyl stearate, Sebacic acid derivatives, Triniethylol ethane tri caprylate caprate, Trimethylol propane triheptanoate, Plithalic acid derivatives, Paraffin derivatives, Isooctyl palmitate, Oleic acid derivatives, Lauric acid derivatives, Isoplithalic acid, Isobutyric acid derivatives, and Adipic acid derivatives, Linear dibasic ester, Glycol derivatives, Glycerol triacetate, Diisodecyl glutarate, Didecyl glutarate, Hydrogenated terphenyl, Benzoic acid derivatives, and Adipic acid derivatives. The most preferred plasticizer for use in the present invention is N-n-butyl benzosulfonamide.

In addition to plasticizers, the present invention may contain stabilizers that stabilize the material with respect to thermal degradation, light and U.V. radiation. Preferred stabilizers that may be used in the present invention include Benzotriazole, p-(p-tolysulfonylamodo)-diphenylamine, Alkylated phenol antioxidant, hindered polyphenols (e.g. Iranox brand), alkylated aryl phosphates (e.g. Celogen R.A. brand), Tris (2-chloroethyl), and p-tuloenesulfony semicarbazide. The most preferred stabilizer for use in the present invention is Benzotriazole. Also, the balloon material may also



include other components including radio-opaque substances and pigment, as is known in the arts.

The preferred embodiment of the invention is composed of plasticized polyamide Nylon 12, N-n-butyl benzosulfonamide (i.e. BBSA) as a plasticizer and benzotriazole as a stabilizer. The preferred amount of plasticizer is about 13% by weight and the preferred amount of stabilizer is less than about 1% by weight. Table 1 summarizes properties of this plasticized Nylon 12 material.

TABLE I

Properties	Standard (ISO)	Unit	Data
Melting Range	-	°C	160-170
Density	R1183	g/cm <sup>3</sup>	1.02-1.03
Water Absorption	62	mg	10
Maximum Water Absorption (conditioned at 23/50 r.h.)	-	%	0.6
Maximum Water Absorption (conditioned at 23/100 r.h.)	-	%	1.2
Tensile Stress at Yield	R527	N/mm <sup>2</sup>	25
Elongation at Yield	-	%	25
Tensile Stress at Break	-	N/mm <sup>2</sup>	27
Elongation at Break	-	%	300
Flexural Modulus of Elasticity	-	N/mm <sup>2</sup>	330
Tensile Modulus of Elasticity	-	N/mm <sup>2</sup>	300
Flexural Stress at 3.5% Strain	178	N/mm <sup>2</sup>	11
Ball Indentation Hardness (H 358/30)	2039	N/mm <sup>2</sup>	40
Shore Hardness D	868	-	61

	Heat Deflection Temperature (Method A)	75	° C	55
	Heat Deflection Temperature (Method B)	75	° C	125
5	Vicat Softening Temperature (A/50)	306	° C	160
	Vicat Softening Temperature (B/50)	306	° C	130
	Coefficient of Linear Thermal Expansion at 23° C	-	$10^{-5}K^{-1}$	18
	Thermal Conductivity	-	W/m K	0.3
10	Abrasion (Taber)	-	mg/100 turns	15
	Impact Strength at 23 to -40° C	179	$kJ/m^2$	no break
	Double-V-notched impact Strength (Radius=0.25 mm) at 23° C	-	$kJ/m^2$	no break
	at 0° C	-	$kJ/m^2$	90
15	at -20° C	-	$kJ/m^2$	15
	at -40° C	-	$kJ/m^2$	9

Regarding the glass transition temperature of plasticized Nylon 12, Figure 1 is a plot graph of the dynamic shear modulus as a function of the temperature for the plasticized Nylon 12. This graph shows the dynamic shear modulus has a maximum 10 at a temperature of about 18°C. This indicates that the plasticized Nylon 12 has a glass transition temperature of about 18°C. The glass transition temperature of plasticized Nylon 12 is therefore substantially less than body temperature (37°C) and substantially less than  $T_g$  for unplasticized Nylon 12 homopolymer. As a result of the materials lower  $T_g$ , a balloon fabricated from this material is extremely flexible and pliant when in a patient at body temperature. Additionally, a plasticized nylon balloon has other advantageous properties including strength

to withstand required inflation pressures and nondistensability as is shown in Figure 2 below.

Figure 2 is a compliance chart for three balloons of different outer diameters fabricated from plasticized Nylon 12 which demonstrates distensibility. Curve 20 shows the compliance characteristics for a 2.5 mm diameter balloon; curve 30 a 3.0 mm diameter balloon; and curve 40 a 3.5 mm diameter balloon. This figure shows a plot of balloon diameter in inches as a function of inflation pressure and the results demonstrate that the balloons of the present invention are substantially non distensible. In effect, the balloon diameter changes only slightly as a function of increased pressure. Furthermore, this chart shows that the balloon's diameter can be expanded in a controlled manner by increasing the inflation pressure, as is advantageous for angioplasty balloons.

**Comparison of a Balloon According to the Present Invention  
and a Nylon 12 Homopolymer Balloon**

Table II represents the results of comparative tests of Nylon 12 homopolymer balloons and one embodiment of the present invention: plasticized Nylon 12 balloons.

TABLE II

Properties	Unit	Nylon 12 Homopolymer	Plasticized Nylon 12
Melting Temperature of Material	°C	172 to 180	160 to 170
Tensile strength at break	N/mm <sup>2</sup>	50 to 55	27
Tensile modulus of elasticity	N/mm <sup>2</sup>	1400 to 1600	300
Glass transition temperature	°C	37 to 42	15 to 20
Flexural modulus of elasticity	N/mm <sup>2</sup>	1400 to 1600	330
Shore hardness D	-	73 to 75	61 to 63
Elongation at break	%	<200	300

These results show that balloons of the present invention are more flexible and pliant than the Nylon 12 homopolymer balloons as represented by the tensile modulus and flexural modulus of the materials. Table II also shows that the glass transition temperature of balloons of the present invention is substantially lower than Nylon 12 homopolymer balloons.

Additionally, Figure 3 shows a relative compliance chart of one embodiment of the present invention as compared with other polymer balloons all of 2.5 mm outer diameter. The curves represent the balloon materials as follows: curve 50 represents an embodiment of the present invention; curve 60 represents Nylon 12 homopolymer; curve 70 represents polyvinylidene fluoride and curve 80 represents PET. As Figure 3 shows, a plasticized Nylon 12 balloon has compliance characteristics similar to that of conventional non-distensible homopolymer balloon materials.

Finally, regarding the softening temperature range of the material of the present invention, Figure 4 is a differential scanning calorimetry (DSC) plot of heat flow as a function of temperature. The curves represent the balloon materials as follows: curve 90 represents one embodiment of the present invention; and curve 100 represents Nylon 12 homopolymer. As this figure indicates, the plasticized Nylon 12 has a lower and less defined softening temperature than the Nylon 12 homopolymer. The softening and melting characteristics differences that result from the addition of plasticizer are advantageous properties in the balloon manufacturing process as is discussed in detail below.

#### **Fabrication of Balloons According to the Present Invention**

The balloons of the present invention not only possess material properties superior to previous balloons but also possess advantages in the manufacturing process of the balloons. Specifically, the materials in the present invention do not crystallize rapidly after being heated so that the

balloons do not have to be immediately cooled. This is an important advantage in the balloon fabrication process.

5 In a particular embodiment of the present invention, medical device balloons are fabricated as follows: The plasticized material is preformed as pellets. The plasticized polymer is heated to a temperature between about 400°F and 445°F and extruded into a tube. The tubing may be extruded in a conventional manner i.e. by forcing the heated material through a die. In one embodiment of the invention the extruded tube has an inner diameter of about 0.017". The outer diameter of the tube varies depending on the required  
10 outer diameter of the balloon. For example, an extruded tube with an outer diameter of about 0.032" may be used for 2.5 mm balloon. The plasticized polymer may also include other components such as stabilizers, fillers and other additives.

15 Another advantage of the present invention is that the presence of moisture has little effect on the material. In contrast, Nylon 12 homopolymer material easily degrades in the presence of moisture. The moisture tolerance of plasticized Nylon 12 is advantageous in both the cost and the ease of manufacturing balloons. For example, when Nylon 12 homopolymer tubing is extruded, the nylon feedstock (i.e. the nylon material before it is heated and extruded) in the hopper must be maintained in a moisture free  
20 environment. This is usually accomplished by using a dryer and heater attached to the hopper. The dryer usually maintains the Nylon 12 homopolymer at about 250°F. However, even with these precautions, the Nylon 12 homopolymer must be used within about 1½ to 2 hours or it will  
25 degrade and become unusable.

By contrast, the plasticized Nylon 12 material can be in the presence of moisture and unused for days without degrading. As a result, there is a great cost savings in manufacturing because heaters and dryers are not necessary. Additionally, the plasticized material may remain in the hopper

for a length of time and still be usable which is both cost saving and convenient in that it maybe used as needed.

Once the plasticized material tubing has been extruded, it is then placed into a mold. Figure 5 is a schematic of an apparatus 130 for balloon fabricating according to one embodiment of the present invention. The apparatus 130 includes a mold block 140 which includes a mold 150, a heater 160 and a cooler 170 fed via pipes 180 and 190. The tubing 200 is placed in the mold and secured by a clamp 210. During molding, the tubing is maintained straight and taught by applying a force to the unclamped end of the tubing 220. The balloon is molded by heating the mold to a temperature in the range of about 240°F to 290°F. At the same time the tubing is pressurized using air or other pressurized fluid. About 210 psi is preferred for a 2.5 mm outside diameter balloon. The tubing is pressurized by introducing the pressurized air into the tube via opening 230. The preferred mold temperature is about 275°F for a 2.5 mm diameter balloon. The material must be heated to within its softening temperature range in order to fabricate a balloon. When the material is at softening temperature, the balloon is fabricated by pressurizing the tubing to conform it to the mold. For the preferred plasticized Nylon 12 balloons, the softening temperature range is between about 240°F and about 325°F.

After the balloon has been blown, it is cooled to within its setting temperature range. The setting temperature is the range within which the crystallization of the balloon material is halted and the balloon expansion is stopped. For the preferred plasticized Nylon 12 balloons, the setting temperature range is between about 100°F and about 135°F. With the present invention, the balloon is preferably cooled to about 100°F.

As discussed previously, it is imperative to prevent crystallization to develop viable balloons. If the balloon material is allowed to crystallize the resulting balloon is rigid and may have weak areas at the crystallization sites.

The conventional Nylon 12 homopolymer material crystallizes rapidly and must be cooled with in about 10 seconds to prevent the balloon material from crystallizing. It can be difficult and more expensive to quickly cool this material in time.

5           In contrast, the plasticized Nylon 12 must be cooled with in 3 to 4 minutes to prevent crystallization. The present invention's extra cooling time makes balloon fabrication considerably easier than the previous material. Since the present invention does not need rapid cooling, the molding apparatus need not be as sophisticated. Therefore, the molding process is  
10 easier and less costly.

          Once a balloon made of the present invention is cooled, it may be removed from the mold for post processing procedures. The balloon may be cut from tubing and then attached to the appropriate medical device. For example, the balloon may be attached to an catheter lumen using convention  
15 methods for use in angioplasty or stent delivery.

          As described above, medical balloons fabricated from the present invention possess many advantageous properties. The balloons are both non-distensible and strong enough to withstand working pressures required for medical balloons. They are also more flexible and pliant than conventional  
20 homopolymer balloons, which allows easier negotiation of narrow coronary vessels. Also since the material does not rapidly crystallize, the cooling time is less critical. Finally, the plasticized material is less moisture sensitive than the conventional Nylon 12 homopolymer and is not degraded in the presence of moisture. All of these advantages lead to a medical device balloon that is  
25 easier and less costly to manufacture than conventional homopolymer balloons. At the same time the balloons possess the qualities of strength, non-distensibility and flexibility necessary for quality medical balloons.

**CLAIMS**

What is claimed is:

- 5 1. A balloon for use in a medical device, the balloon being made of a material comprising a plasticized polyamide or plasticized polyester, the material having a glass transition temperature of less than about 32°C.
- 10 2. A balloon according to claim 1, wherein the glass transition temperature of the material is between about 10°C and about 32°C.
- 15 3. A balloon according to claim 1, wherein the material comprises a plasticized polyamide.
- 20 4. A balloon according to claim 3, wherein the plasticized polyamide includes Nylon 11 homopolymer, Nylon 12 homopolymer, or mixtures thereof.
- 25 5. A balloon according to claim 3, wherein the plasticized polyamide includes a polyamide homopolymer and a plasticizer selected from the group consisting of N-n-butyl benzosulfonamide, N-n-butyl stearate, Sebacic acid derivatives, Trimethylol ethane tri caprylate caprate, Trimethylol propane triheptanoate, Phthalic acid derivatives, Paraffin derivatives, Isooctyl palmitate, Oleic acid derivatives, Lauric acid derivatives, Isophthalic acid derivatives, Isobutyric acid derivatives, Linear dibasic ester, Glycol derivatives, Glycerol triacetate, Diisodecyl glutarate, Didecyl glutarate, Hydrogenated terphenyl, Benzoic acid derivatives, and Adipic acid derivatives.



6. A balloon according to claim 5, wherein the plasticizer is N-n-butyl benzosulfonamide.

5 7. A balloon according to claim 3, wherein the plasticized polyamide further includes a stabilizer selected from the group consisting of Benzotriazole, p-(p-tolysulfonylamodo)-diphenylamine, Alkylated phenol antioxidant, hindered polyphenols, alkylated aryl phosphites, Tris (2-chloroethyl), and p-tuloenesulfony semicarbazide.

10 8. A balloon according to claim 7, wherein the stabilizer is benzotriazole.

9. A balloon according to claim 1, wherein the material has a tensile modulus of elasticity of less than about 650 N/mm<sup>2</sup>.

15 10. A balloon according to claim 1, wherein the material has a flexural modulus of elasticity of less than about 650 N/mm<sup>2</sup>.

20 11. A balloon according to claim 1, wherein the material has an elongation at break of less than about 325%.

12. A balloon according to claim 1, wherein the material comprises plasticized PET.

25 13. A balloon according to claim 4, wherein the plasticized polyamide includes Nylon 12 homopolymer, N-n-butyl benzosulfonamide, and benzotriazole.

14. A balloon according to claim 13, wherein the N-n-butyl benzosulfonamide constitutes about 13% by weight of the plasticized polyamide and the benzotriazole constitutes less than about 1% by weight of the plasticized polyamide.

5

15. A plasticized polyamide balloon made of a material comprising a polyamide homopolymer, N-n-butyl benzosulfonamide, and benzotriazole.

10

16. A balloon according to claim 15, wherein the polyamide homopolymer is Nylon 12 homopolymer.

15

17. A balloon according to claim 15, wherein the N-n-butyl benzosulfonamide constitutes about 13% by weight of the material, and the benzotriazole constitutes less than about 1% by weight of the material.

18. A method for making a balloon for use in a medical device, the method comprising the steps of:

20

(a) providing a tube made of a material comprising a plasticized polyamide or plasticized polyester as described in claim 1, the material having a softening temperature range and a setting temperature range;

(b) disposing the tube in a balloon mold;

25

(c) heating the tube to a temperature within the softening temperature range of the material;

(d) pressurizing the tube to conform it with the mold, thus producing a balloon;

- (e) cooling the balloon to a temperature within the setting temperature range of the material; and
- (e) removing the balloon from the mold.

- 5 19. A method according to claim 18, wherein the balloon provided in step (a) is made of a material comprising Nylon 12 homopolymer and N-n-butyl benzosulfonamide, the material having a softening temperature range of from about 275°F to about 325°F and a setting temperature range of from about 100°F to about 135°F.

## AMENDED CLAIMS

[received by the International Bureau on 02 April 1998 (02.04.98);  
original claims 1-19 replaced by amended claims 1-17 (3 pages)]

What is claimed is:

1. A balloon for use in a medical device, the balloon being made  
of a material comprising a plasticized polyamide, the material having  
a glass transition temperature of less than about 32°C.
2. The balloon according to claim 1, wherein the glass transition  
temperature of the material is between about 10°C and about 32°C.
3. The balloon according to claim 1, wherein the plasticized  
polyamide includes Nylon 11 homopolymer, Nylon 12 homopolymer,  
or mixtures thereof.
4. The balloon according to claim 1, wherein the plasticized  
polyamide includes a polyamide homopolymer and a plasticizer  
selected from the group consisting of N-n-butyl benzosulfonamide, N-  
n-butyl stearate, Sebacic acid derivatives, Trimethylol ethane tri  
caprylate caprate, Trimethylol propane triheptanoate, Phthalic acid  
derivatives, Paraffin derivatives, Isooctyl palmitate, Oleic acid  
derivatives, Lauric acid derivatives, Isophthalic acid derivatives,  
Isobutyric acid derivatives, Linear dibasic ester, Glycol derivatives,  
Glycerol triacetate, Diisodecyl glutarate, Didecyl glutarate,  
Hydrogenated terphenyl, Benzoic acid derivatives, and Adipic acid  
derivatives.
5. The balloon according to claim 4, wherein the plasticizer is N-  
n-butyl benzosulfonamide.
6. The balloon according to claim 1, wherein the plasticized  
polyamide further includes a stabilizer selected from the group  
consisting of Benzotriazole, p-(p-tolysulfonylamodo)-diphenylamine,

Alkylated phenol antioxidant, hindered polyphenols, alkylated aryl phosphites, Tris (2-chloroethyl), and p-tuloenesulfony semicarbazide.

7. The balloon according to claim 6, wherein the stabilizer is benzotriazole.

5 8. The balloon according to claim 1, wherein the material has a tensile modulus of elasticity of less than about 650 N/mm<sup>2</sup>.

9. The balloon according to claim 1, wherein the material has a flexural modulus of elasticity of less than about 650 N/mm<sup>2</sup>.

10 10. The balloon according to claim 1, wherein the material has an elongation at break of less than about 325%.

11. The balloon according to claim 5, wherein the plasticized polyamide includes Nylon 12 homopolymer, N-n-butyl benzosulfonamide, and benzotriazole.

15 12. The balloon according to claim 11, wherein the N-n-butyl benzosulfonamide constitutes about 13% by weight of the plasticized polyamide and the benzotriazole constitutes less than about 1% by weight of the plasticized polyamide.

20 13. The plasticized polyamide balloon made of a material comprising a polyamide homopolymer, N-n-butyl benzosulfonamide, and benzotriazole.

14. The balloon according to claim 13, wherein the polyamide homopolymer is Nylon 12 homopolymer.

15. The balloon according to claim 13, wherein the N-n-butyl benzosulfonamide constitutes about 13% by weight of the material, and the benzotriazole constitutes less than about 1% by weight of the material.

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16. A method for making a balloon for use in a medical device, the method comprising the steps of:

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- (a) providing a tube made of a material comprising a plasticized polyamide or plasticized polyester as described in claim 1, the material having a softening temperature range and a setting temperature range;
- (b) disposing the tube in a balloon mold;
- (c) heating the tube to a temperature within the softening temperature range of the material;
- (d) pressurizing the tube to conform it with the mold, thus producing a balloon;
- (e) cooling the balloon to a temperature within the setting temperature range of the material; and
- (f) removing the balloon from the mold.

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17. The method according to claim 15, wherein the balloon provided in step (a) is made of a material comprising Nylon 12 homopolymer and N-n-butyl benzosulfonamide, the material having a softening temperature range of from about 275°F to about 325°F and a setting temperature range of from about 100°F to about 135°F.

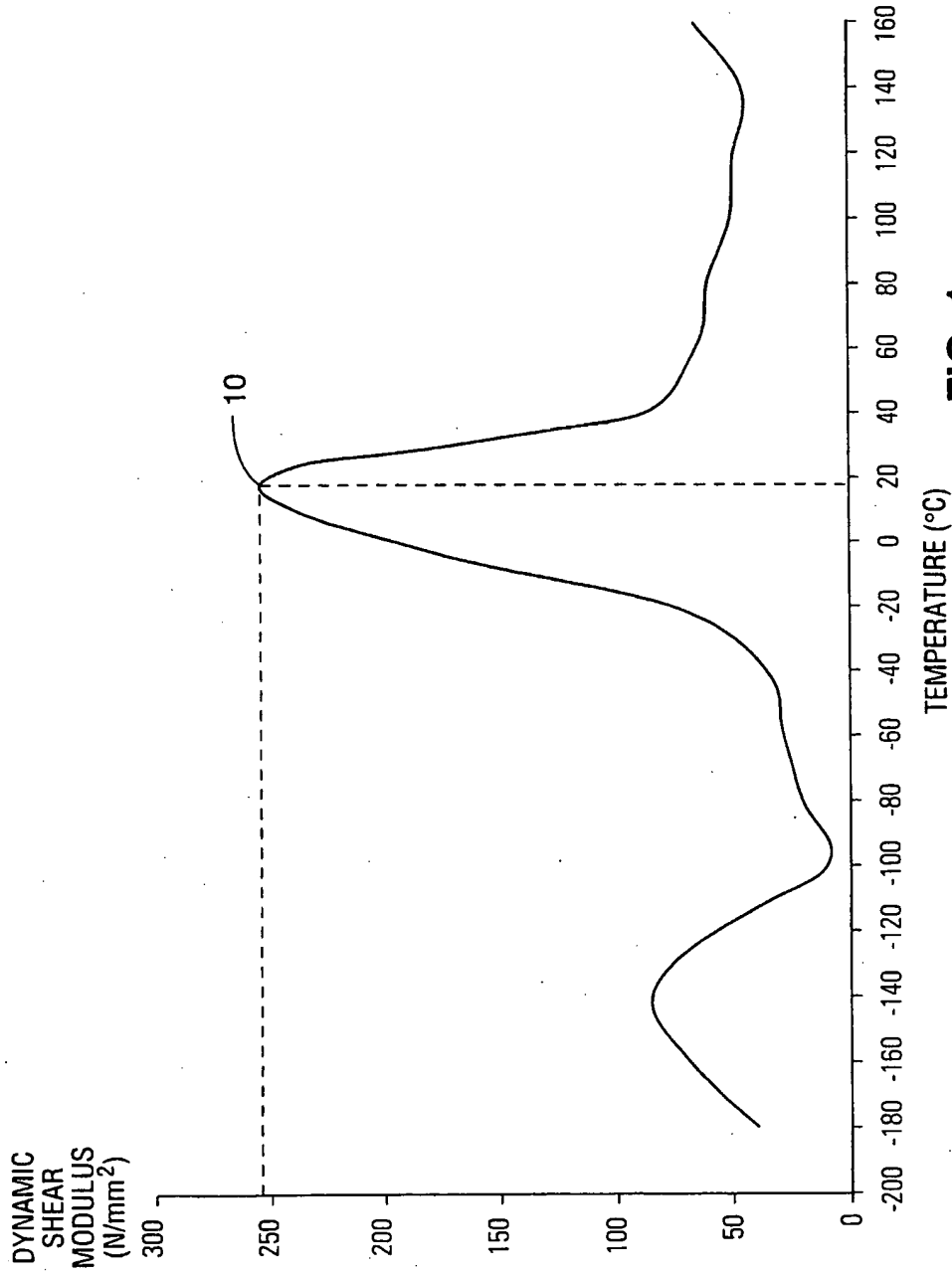


FIG. 1

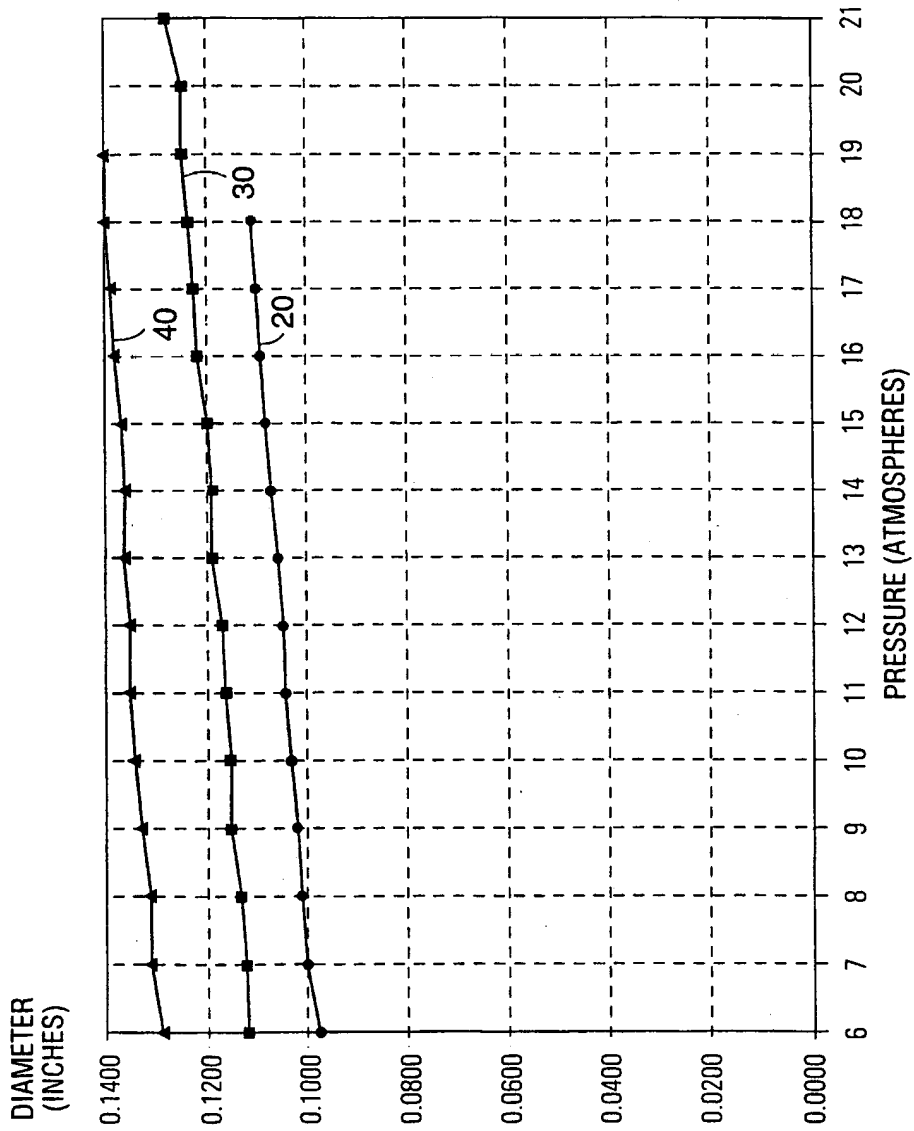


FIG. 2



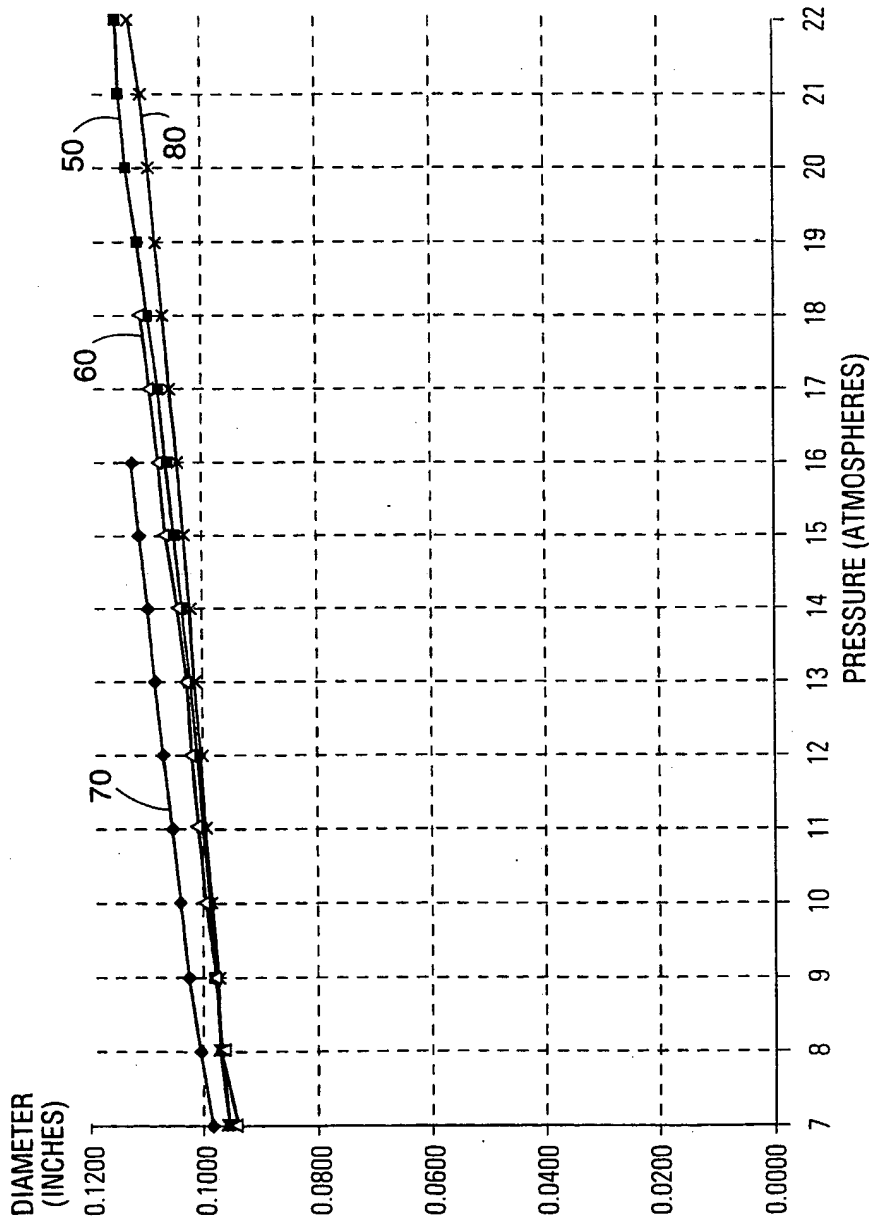


FIG. 3

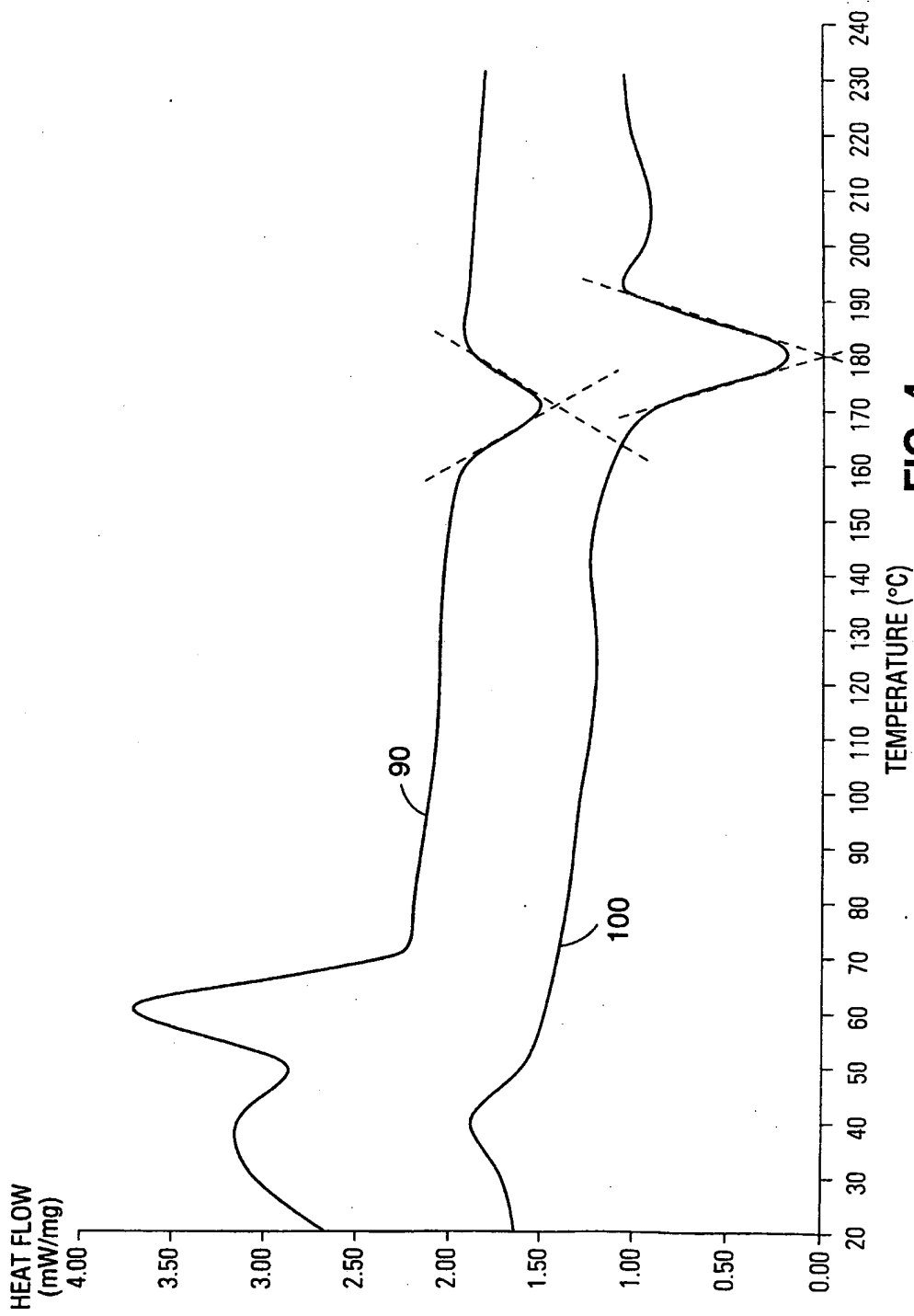


FIG. 4

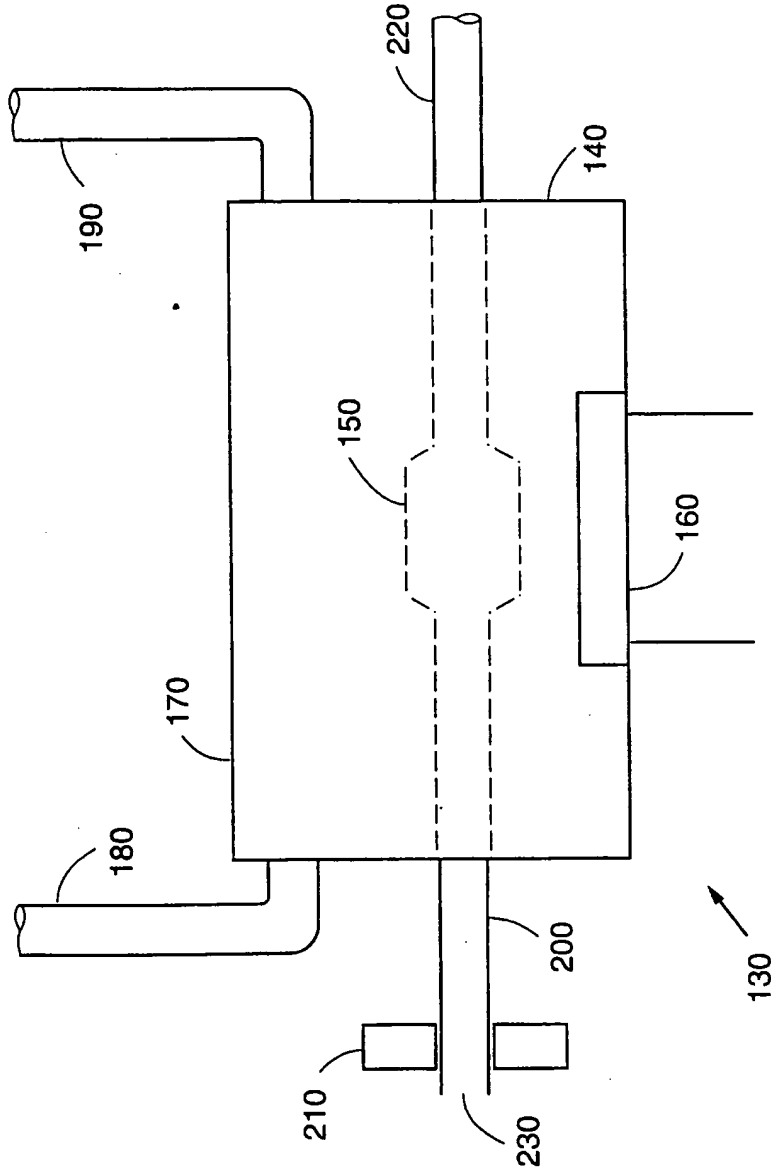


FIG. 5

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 97/17275

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 6 A61L29/00 C08K5/00 C08K5/435		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61L C08K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 514 913 A (NOVOSTE CORP) 25 November 1992 see column 11, line 40 - line 53 see column 14, line 2 - line 23 see examples 5,7 ---	1,3-6,11
Y	EP 0 362 826 A (CORDIS CORP) 11 April 1990 cited in the application  see column 6, line 6 - column 9, line 12 see column 13, line 30 - line 49 ---	1,3-6, 11,12, 18,19
Y	PATENT ABSTRACTS OF JAPAN vol. 006, no. 044 (C-095), 19 March 1982 & JP 56 161426 A (TORAY IND INC), 11 December 1981, see abstract  ---	1,3-6, 11,18,19
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		
<input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents :		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search  <p style="text-align: center;">23 January 1998</p>	Date of mailing of the international search report  <p style="text-align: center;">05/02/1998</p>	
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016	Authorized officer  <p style="text-align: center;">Heck, G</p>	

INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/US 97/17275

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 214 112 A (MONSANTO CO) 11 March 1987 see abstract see page 2, line 34 - line 56 ---	12
A	MARK H..F. ET AL: "ENCYCLOPEDIA OF POLYMER SCIENCE AND ENGINEERING", JOHN WILEY & SONS., NEW YORK (US) XP002053155 see page 348, paragraph 2 - page 349, paragraph 2 see page 370, paragraph 2 - paragraph 3; table 21 see page 464; table 8 -----	1,2,9-11

**INTERNATIONAL SEARCH REPORT**

International Application No

PCT/US 97/17275

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0514913 A	25-11-92	DE 69218039 D	17-04-97
		DE 69218039 T	09-10-97
		ES 2101769 T	16-07-97
		JP 5064660 A	19-03-93
		US 5484565 A	16-01-96
EP 0362826 A	11-04-90	US 4906244 A	06-03-90
		DE 8916076 U	22-07-93
		DE 68928072 D	03-07-97
		DE 68928072 T	02-10-97
		EP 0436501 A	10-07-91
		US 5356591 A	18-10-94
		US 5449371 A	12-09-95
		US 5108415 A	28-04-92
		US 5156612 A	20-10-92
		US 5236659 A	17-08-93
		US 5304197 A	19-04-94
		JP 3057462 A	12-03-91
		EP 0214112 A	11-03-87
JP 7002900 B	18-01-95		
JP 62043449 A	25-02-87		